

REMARKS

Applicants respectfully request entry of the amendment and reconsideration of the claims. Claim 17 has been amended. Claims 1-14, 19, 21-22, and 26-34 have been canceled without prejudice. Applicants reserve the right to pursue the canceled subject matter in a continuation application. After entry of the amendment, claims 17, 20, 23-25, and 35 will be pending. Applicants submit the amendment places the claims in condition for allowance.

Double Patenting

Claims 17, 20, and 23-25 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 15-18, 20, and 23-25 of copending Application No. 10/663,158. Applicants respectfully traverse the rejection.

If a provisional non-statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications and the later-filed application is rejectable on other grounds, the Examiner should withdraw the provisional ODP rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer. MPEP § 804(I)(B)(1). Applicants note that the present application was filed on March 20, 2002, while copending Application No. 10/663,158 was filed on September 15, 2003. The present application is therefore the earlier filed of the two applications.

Applicants submit the claims as amended are in condition for allowance. Withdrawal of the rejection is respectfully requested.

Enablement

Claims 17, 20, 23-25, and 35 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Applicants respectfully traverse this rejection.

An enabling disclosure requires a reasonable correlation to the scope of the claims. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied (*In re Fischer*, 427 F.2d 833, 839 (CCPA 1970)).

Claim 17 as amended recites a method for treating an allergic disorder. Allergic disorders are characterized by enhanced Th2 response and overproduction of Th2 cytokines.

With respect to allergic disorders, Example 3 and Figs. 11A and 11B demonstrates the Th2 response is regulated at least in part by TCCR activity and suggests that a TCCR agonists would be useful for treating allergic disorders, such as asthma. The specification teaches methods for making and identifying TCCR agonists, including agonist antibodies. See, for example, the specification at page 63, line 16 to page 66, line 1 and page 67, lines 2-5.

The contemporaneous publication of Huang et al., 2001, *J. Immunol.*, 166: 207-217 (copy enclosed) further supports Applicants' claims. Huang demonstrated that Th1 cells can counteract Th2-mediated asthma in a rat model. Further, Huang's model is particularly relevant to treatment of clinical asthma because down-regulation occurred at the efferent or elicitation phase of the responses when Th2 cells are fully developed and capable of promoting asthma.

Therefore, in view of the guidance and working examples provided by the specification and knowledge in the art, it was reasonable to expect that an allergic disorder could be treated without undue experimentation by administering a TCCR agonist.

The Office alleges the post filing reference of Lucas does not diminish the unpredictability of the effects of a TCCR agonist antibody *in vivo* because IL-27 alone cannot induce Th1 differentiation. Applicants respectfully do not agree and submit the teachings of the specification are confirmed by subsequent post-filing publications. Artis et al., 2004, *J. Immunol.*, 173:5626-5634 (copy enclosed) discloses addition of recombinant IL-27, a TCCR agonist, to wild type T cell cultures led to a 30% reduction in the frequency of CD4+ T cells producing IL-4 (a Th2 cytokine). Applicants demonstrate in U.S. 2006/0177436 that administration of the TCCR agonist IL-27 inhibits proliferation of wild type Th2 cells (see, for example, working example 8 and Fig. 19).

Applicants respectfully request that the Examiner give full consideration to the remarks and evidence provided herein. To the extent a document is submitted as evidence directed to an issue of patentability raised in an Office Action, and the evidence is timely presented, applicant need not satisfy the requirements of 37 C.F.R. §1.97 and 37 C.F.R. §1.98 in order to have the Examiner consider the information contained in the document relied upon by applicant (MPEP § 609.05(c)).

In view of the forgoing, Applicants submit the claims can be practiced without undue experimentation. The guidance and working examples provided in the specification establish a

reasonable expectation for treating an allergic disorder with a TCCR agonist, and the post filing publications of Artis et al. and U.S. 20060177436 confirm Applicants' teachings. Accordingly, withdrawal of the rejection is respectfully requested.

Anticipation

Claim 17 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. 5,792,850 (hereinafter the '850 patent). Without acquiescing to the rejection and solely for the purpose of advancing prosecution, claim 17 is now directed to methods of treating an allergic disorder by administering a TCCR agonist. Applicants reserve the right to pursue the canceled subject matter in a continuation application.

In order to anticipate a claim, the prior art reference must teach each and every element of the claim. *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987; MPEP § 2131. The '850 patent does not teach, either expressly or inherently, treating an allergic disorder with a TCCR agonist. Accordingly, withdrawal of the rejection is respectfully requested.

Summary

In view of the above amendments and remarks, Applicants respectfully submit the claims are in condition for allowance and request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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